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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/913,643 | 10/19/2001 | Mika Jokinen | TUR -115 | 4103 |

7590 08/26/2004
James C Lydon
Suite 100
100 Daingerfield Road
Alexandria, VA 22314

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/913,643 | Applicant(s) JOKINEN ET AL. | |
| | Examiner Blessing M. Fubara | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/06/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 16-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 16-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for petition to withdraw from issue filed 05/06/04, which request was granted 05/07/04; request for continued examination, preliminary amendment and remarks filed 05/06/04 and English translation of selected relevant sections of DE 19609551 and supplemental remarks filed 07/20/04. Claims 1, 3-7 and 16-33 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicants' submission filed on 05/06/04 has been entered.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US 4,919,871).

Lin discloses a method of preparing fibers from sol-gel compositions and the method comprises dry spinning sol of suitable viscosity through an orifice (abstract, column 2, lines 19-27). The sol-gel of Lin is prepared from tetraethoxysilane (TEOS), ethylsilicate 40, which is a partially condensed tetraethylorthosilicate (TES) (column 2, lines 28-66) and the sol is a silica sol since it is formed from silicates. The sol formed in example XII is aged to a room

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temperature viscosity of 129 poise (12900 mPa.s) and the composition is formed or spun into fibers at said viscosity of 129 poise. See also claims 1-8 of Lin. The viscosity of 129 Poise or 12,900 mPa.s is below 100,000 mPa.s but lies between the viscosity ranges in claims 3-7. Lin discloses fibers that are obtained from sol and thus meets the limitations of the scope of the claim. Thus, in light of the above discussion, Lin meets the limitations of the claims.

4. Claims 1, 3-7 and 16-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahola et al. (WO 97/45367).

Ahola discloses silica-xerogels produced by sol-gel process (abstract, page 1, lines 22-30 and claim 1). In Ahola the sol is formed into small particles by spray drying or fiber spinning or by drawing technique (page 3, lines 29-33). Ahola discloses sustained and/or controlled release delivery devices comprising the silica-xerogel particles and biological agents; Ahola discloses a method of administering biologically active agents to a human or animal where the method comprises implanting or injecting or transmucosally attaching to a human or animal body a delivery device, wherein the delivery device comprises silica-xerogel that undergoes controlled dissolution and where the silica-xerogel particle/fiber spun from a sol-gel comprises has biologically active agent incorporated therein (page 4, lines 1-18 and claims 13-22). Ahola discloses that silica-xerogel particles undergo controlled dissolution over a period of time and that the biologically active agents incorporated into the particles also undergo controlled release (page 4, line 25 to page 5, line 27). Ahola further discloses production of fibers from the silica-xerogels by sol-spinning technique conducted at room temperature (page 9, line 27 to page 10 line 17). In example 2, Ahola produces silica fibers by drawing the fibers in spinneret reactor at a starting sol viscosity of 10 mPa.s and this viscosity is less than 100,000 mPa.s. A viscosity of

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10 mPa.s also lies within the viscosity ranges of 1,000 to 15,000 mPa.s and 2,000 to 50,000 mPa.s.

Reading claims 16 and 20 in light of the specification clearly shows that the method for controlling the biodegradation of silica fiber is related to the dissolution of the silica fiber and said dissolution is influenced by the viscosity at which spinning begins (example 3 of the instant specification). Ahola also teaches that the silica-xerogel or the silica-xerogel fiber comprising biologically active agents undergoes controlled dissolution and controlled release of the biologically active agents. Since the silica-xerogel fiber of Ahola is produced by spinning the sol-gel and since the spinning starts at a specific viscosity that accords the fiber its properties, Ahola inherently teaches the method of claims 16 and 20 and the viscosity of 10 mPa.s at which the spinning starts in Ahola meets the viscosity limitations of claims 2-7, 9-11, 13-15, 17-19 and 21-23.

Thus Ahola anticipates the claims as discussed above.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3-7 and 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 196 09 551, English translation of selected sections provided by applicants.

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The DE reference discloses a method of preparing a fiber from hydrolytically condensable silicon compounds and the formed fibers have tensile strength ranging from 100-800 Mpa. The DE reference discloses that degree or extent of polycondensation controls the biodegradability of the fibers. See translation provided by applicants. The DE reference differs from the instant claims in that the DE reference discloses a viscosity of from 100-800 Mpa while the viscosity in the instant claims is from 1000-100,000 Mpa. There is no demonstration in applicants specification that the viscosity range recited provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare silica fibers as disclosed by the DE reference. One having ordinary skill in the art would have been motivated to prepare the silica fibers from silica solutions that have the appropriate viscosities with the expectation of obtaining fibers that have controlled biodegradation rate.

Applicants argue in the supplemental remarks that the DE reference fails to disclose that controlling the viscosity of the silica sol from which the fibers are spun can allow the biodegradability of the fiber and that the instant spun fiber dissolves in 21 days while the spun fiber of the DE reference dissolves in 50 days.

7. Applicants' arguments filed 07/20/04 have been fully considered but they are not persuasive. Applicants have not provided a showing that a fiber dissolving completely within 21 days has unusual advantages over fiber that dissolves completely within 50 days.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

